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Older people's experiences of changed appearance of medications due to generic prescribing: a qualitative study

FINAL REPORT

Tracey Williamson
Michelle Howarth
Leah Greene
Arvin Prashar

March 2010

Faculty of Health and
Social Care

Contact the School of Nursing:

Tel: +44(0)845 234 0184
E-mail: fhsc@salford.ac.uk

Contact the Salford Centre for Nursing & Midwifery Research:

Wendy Moran
Tel: +44(0)161 295 2768
E-mail: w.e.moran@salford.ac.uk

<http://www.nursing.salford.ac.uk/>

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This report can be referenced as Williamson, T; Howarth, M; Greene, L; and Prashar, A (2010) *Older people's experiences of changed appearance of medications due to generic prescribing: a qualitative study. Final report*, University of Salford

ISBN: 978-1-905732-87-6

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Dr Tracey Williamson

Research Fellow Older People/User Involvement
Salford Centre for Nursing & Midwifery Research
University of Salford

Michelle Howarth

Lecturer
School of Nursing & Midwifery
University of Salford

Leah Greene

Simulation Laboratory Coordinator
School of Nursing & Midwifery
University of Salford

Arvin Prashar

Research Fellow
Salford Centre for Nursing & Midwifery Research
University of Salford

Project advisors:

Vivienne Ben-David*

Chris Houston

Martin Johnson**

Steve Pugh**

Julia Ryan**

Fred Schofield

Gill Shaw***

*** NHS Heywood, Middleton & Rochdale **University of Salford**

***** NHS Tameside & Glossop**

Contents

		Page
CONTENTS		2
ACKNOWLEDGEMENTS		5
PART 1 – Introduction		6
PART 2 – Literature Overview		9
	Medication management and safety in older people	9
	Polypharmacy	10
	Medication compliance and concordance	12
	Tablets: packaging, preferences and price	13
	Conclusion	15
PART 3 – Study Design		16
	Study aims	16
	Older people's involvement	16
	Sampling	17
	Interview guide	17
	Data collection	18
	• Procedure	18
	• Use of video / audio recordings	19
	Data analysis	19
	Ethical considerations	20
	• Approvals	20
	• Issues	20
	Study limitations	20

PART 4 – Findings		22
	The importance of routine	22
	• Managing appearance changes	23
	- <i>Colour</i>	23
	- <i>Shape</i>	27
	- <i>Packaging</i>	27
	• Managing access	29
	- <i>Size</i>	31
	Confidence	33
	• Confidence in self	33
	• Confidence in others	33
	• Confidence in medications	36
	Being 'old'	48
	Retaining control	52
PART 5 – Discussion		56
PART 6 – Conclusions & Recommendations		60
	Conclusions	60
	Recommendations	63
Appendix	Interview guide	65
References		66
Tables	Table 1 Frequency of concerns	45
	Appearance of changes & impact – summary perspectives	46

Acknowledgements

This study was part funded by the former Greater Manchester Older People's Network and special thanks go to Jean Tottie for valuing the topic and facilitating this funding. Funding was also received from the University of Salford.

We greatly appreciate the help of all participants who took part.

Leah Greene is a developing researcher who has furthered her research skills through involvement in the study as well as contributing greatly to the conduct and success of the study.

Whilst joining the study team latterly, Michelle Howarth has been instrumental to the success of the study and is greatly thanked for her major contribution.

Rochdale User Carer Action Forum members are warmly thanked for informing the study and for providing valuable anecdotal evidence to influence its design. Special thanks to advisors Chris Houston and Fred Schofield.

All other study advisors are also thanked for their valuable input.

Grateful thanks to Paul Gala and colleagues at Age Concern Metro Rochdale for supporting the project and providing meeting facilities.

The Chair and members of Wigan and Leigh Local Research Ethics Committee kindly provided useful advice and support which enhanced the study.

Colleagues from the former Rochdale NSF Older People Local Implementation Team are thanked for backing the study and encouraging the identification of further funding.

Peter Howarth, Prescribing Advisor, NHS Tameside and Glossop, is thanked for his early input to clarify issues concerning parallel imports and generic prescribing.

We are grateful for the contribution of Heywood, Middleton and Rochdale Community Pharmacy Steering Group and Local Pharmaceutical Committee for critically reading the draft report and suggesting amendments.

PART 1

Introduction

When medication is prescribed for a patient it is normally by the generic drug name. It is an NHS directive for prescribers to use the generic drug name unless there is a clinical justification for using the brand name.

This 'generic prescribing' and the Government driving down the value of drug re-imbursement forces both Independent and Multiple Pharmacies to source a medicine of the required quality, at the least cost, in order to not dispense prescriptions at a cost to themselves.

For example, Panadol is the brand name for Paracetamol but it is prescribed as a generic medication at a fraction of the price, and pharmacists are only re-imbursed for the Paracetamol, irrespective of whether Panadol is supplied or not. Supplying Panadol against the generic prescription would be at a cost to the pharmacist. When branded drugs are still in their 'patent' period, which is a number of years after they are introduced into the market, there is only one sole supplier. Expiration of this period allows other manufacturers to 'mimic' the branded product, at a fraction of the cost. This is why the Government insists on generic prescribing, as where the alternatives are available major savings can be made. Generic drug companies must perform tests and show that their drugs are equivalent in terms of therapeutic effect to the brand-name drug. These companies must show that the ingredients of the generic drug enter into the blood stream in the same way and in the same length of time as the brand-name drug.

Meadows (2005) explains that:

'Patent protection gives brand-name manufacturers the right to be the sole source of a drug for a certain time period so they can recoup the money they invested in trying to develop the product.'

However, as soon as this patent protection expires, the generic version of a drug can be sold. Also highlighted are economic

reasons why doctors request generic drugs in preference to brand-name drugs:

'Generic drugs have exactly the same active ingredients and effects as brand-name drugs, but they can cost 30 percent to 80 percent less.'

(Meadows 2005)

It is perhaps important to use generic medication suppliers to reduce prescription costs for the NHS. However, generic manufacturers' packaging changes frequently as each adopts its own product 'house style' and tablet packaging affects medicine compliance.

In England, government policies have pressurised health professionals to issue the least costly version of a medication. Doctors are financially rewarded for keeping prescribing within budgets and pharmacists are forced to source the cheapest available medication due to re-imbursement prices being set after government consultation with manufacturers. However, some manufacturers set their prices higher than those re-imbursed by the Government in an attempt to drive the Government reimbursement up and hence increase their profit margins.

Most recently the Government has outlined proposals concerning the implementation of 'automatic substitution' of some branded medicines for generic ones by pharmacists. As it currently stands it is illegal for pharmacists to supply generic drugs against branded prescriptions.

When people receive their tablet / capsule medicines from their pharmacist, the brand and so the appearance (colour, size, shape) can be vastly different to those dispensed following their previous prescription despite having the same active ingredient. This is often due to a lack of standardisation practice required amongst manufacturers. Drugs are made to British and European Pharmacopoeia standards but these do not specify colour, size and shape. The Directive 2001/83/EC of the European Parliament stated that medicines had to be of 'essential similarity' but that does not include appearance. Many pharmacists believe that standardisation, should not only include size, shape, colour but

also packaging. Packaging changes from the same company on consecutive orders presents considerable challenge to pharmacists as well as patients.

Furthermore, until recently some changes in appearance of tablets and capsules have been due to 'parallel imports'. These are medications that are supplied by parallel importers from Europe which can be re-sold to pharmacies in the UK so long as labelling in English is attached.

Whatever the cause of the changes in appearance of tablets and capsules, substantive anecdotal evidence that the changes presented challenges to many older people was presented to the research team by older people in Rochdale Borough. Members of the Rochdale User Carer Action Forum raised concerns that the changes in appearance of medicines had contributed to people they knew ending up being admitted to hospital due to poor medicine control. They provided examples of older people becoming confused or upset by unexpected changes in the appearance of their prescription medicines. Older people were known to have omitted their medicines for several days until clarity was gained, or for example where a tablet had become smaller, doses were doubled 'just in case'.

Email conversations took place between the project lead and the European Commission and National Patient Safety Agency. It was concluded that whilst these agencies had themselves heard anecdotal evidence of a problem concerning appearance of medicines, there would need to be a substantial body of evidence of significant risk in order to influence the European Union (EU) and national governments to change EU directives concerning medicines.

The research team was approached to see if it could acquire funding to investigate the problem further on behalf of Rochdale User Carer Action Forum members. Funding was gained for a Greater Manchester-wide postal survey (Williamson *et al* 2009) and a further qualitative study presented here. Two older people volunteered to be study advisors to inform the design and conduct of the study.

PART 2

Literature Overview

The following literature overview provides a helpful policy, practice and research context within which these survey findings can be situated. Relevant literature was located concerning four distinct subject areas and each of these will be considered in turn.

- Medication management and safety in older people
- Polypharmacy
- Medication compliance and concordance
- Tablets: packaging, preferences and price

Medication management and safety in older people

As people get older, their use of medicines tends to increase so they need to be sure they have the right medicine, at the right dose and in the right form (Department of Health - DH 2001). Medication mismanagement is an issue that is common amongst some older people and it can initiate adverse drug reactions. As people age, their central nervous system develops increased sensitivity so they are more susceptible to the actions of drugs. The median age of patients admitted to hospital with adverse drug reactions is 76 years old (Pirmohamed *et al* 2004).

According to Teeling and Feely (2005), adverse drug reactions are responsible for approximately 6% of hospital admissions with two particular risk factors being extremes of age and polypharmacy (use of 4 or more drugs). To limit the excessive use of prescription medicines, the DH Medicines and Older People Policy (2001) recommends that *'all people over 75 years should normally have their medicines reviewed at least annually'*.

Another factor that contributes to medication mismanagement is low health literacy. Health literacy can be defined as *'the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions'* (Healthy People 2010, cited in Riley *et al* 2006). Previous studies have found that adverse drug

reactions are related to how medicines are used and low health literacy increases drug use error (Metlay *et al* 2005). Low health literacy means that people may not be able to understand complicated medication instructions. Particular challenges may pertain to understanding of verbal instructions, calculation of medication dosages and understanding of complex delivery systems (Riley *et al* 2006).

Other recognised contributing factors to potential medicines mismanagement include removing medicines from their original containers, poor eyesight, which could limit the ability to read instruction labels, and polypharmacy. Measures needed to be found to identify those patients and aid them. The introduction of Medicine Use Reviews (MURs) from within pharmacy with the New Community Pharmacy Contractual Framework in 2005 was a giant step towards this. Simultaneously, under the Disability Discrimination Act (HMSO) 2005, risk assessments were introduced in community pharmacies to ascertain what level of support patients required. Supportive measures include simple reminder charts, bottles with 'easy open' tops, enhanced labels for poor eyesight, or even talking labels.

Polypharmacy

Polypharmacy is defined by the Department of Health as being '*where a patient is prescribed four or more drugs*' (DH 2001). In their systematic review of the causes and effects of polypharmacy amongst older people, Reid and Crome (2005) define polypharmacy as '*prescription of more drugs than is clinically justified*'. Polypharmacy is not necessarily bad; sometimes it is necessary. However, as previously discussed, polypharmacy can lead to potential harm from medication mismanagement.

Older people form 18% of the population of the UK and polypharmacy is common in this age group as they consume 45% of all drug prescriptions and the average number of prescribed drugs increases with age:

'51% of patients over 65 who receive repeat prescriptions get four or more concurrent repeats.'

(Reid & Crome 2005)

Reid and Crome (2005) mention two main reasons for inappropriate polypharmacy. Firstly, is the failure to discontinue drugs that are no longer necessary, and secondly, is the 'prescribing cascade'. This is where a drug is prescribed that causes a side effect, another drug is then prescribed to counteract the side effect and further side effects follow.

Kippen *et al* (2005) discovered that older people were particularly concerned about taking medication simply to manage side effects from other medication. Reid and Crome (2005) recommend that one way to avoid polypharmacy is to use a single drug to treat more than one clinical problem, for example in the treatment of hypertension and angina. Some older people have also commented that it would be a good idea to combine medicines '*so that tablets that were commonly taken together under the same conditions could be merged and become one 'super-drug'*' (Kippen *et al* 2005). Also, Rudd *et al* (1992) recommended prescribing longer-acting medicines, which would reduce the daily amount of medication required. All of these ideas need to be taken into consideration, to reduce medication mismanagement in older people.

Repeat prescription systems also need to be improved to reduce polypharmacy. This would help by 'synchronising quantities', 'ensuring regular review of the need for each medicine' and 'monitoring that the medicine is being taken and the patient is benefiting from it' (DH 2001). This is the function of community pharmacy MURs.

Reid and Crome (2005) suggest that '*in the next few years prescribing systems will be integrated with electronic patient records to avoid over prescribing and polypharmacy*'. In order to achieve this it will be necessary to grant community pharmacists full access to electronic patient records, so that MURs can be made specific and accurate for individual patients.

There is a strong correlation between non-concordance and polypharmacy. Muir *et al* (2001) found that '*when the complexity of the medication was reduced, concordance with medication improved*'.

Medication compliance and concordance

Often the words compliance and concordance are used interchangeably in relation to medicines. To clarify, the DH (2001) defines medication compliance as *'the extent to which a patient takes or uses a medicine as intended by the prescriber'*. Concordance means *'a partnership between patient and health professional in which an agreement is reached about whether and how medicines are taken/used'* (DH 2001).

Hill and Ball (1992) reported that 25-59% of older individuals do not adhere to medication regimens. Such non-adherence is associated with less favourable patient outcomes (Bainbridge & Ruscin 2009). Kippen *et al* (2005) used focus groups with five groups of participants aged over 60 years to provide valuable insight into reasons why older people do not comply with their medication regimes. These reasons included impact on lifestyle, lack of reliable information about their medicines, debilitating side-effects and issues relating to packaging (Kippen *et al* 2005). These authors also found that many of the older people questioned referred to a 'loss of control' of their lives as they were required to take medicines on a long-term basis. The results showed that there is a need for GPs and pharmacists to give older people clearer information regarding medicines. It was also discovered that the size, shape and packaging of medication can make it difficult to access and as a consequence, accidental non-compliance was commonly reported (Kippen *et al* 2005).

Steinmetz *et al* (2005) discovered that another reason for non-compliance with medication regimes in older people was the lack of specific prescribing information, for example, dosing and safety information, on drug labels. They found that often the package insert contains no information on drug dosing for older people and that the information inserts were difficult to locate (Steinmetz *et al* 2005).

A comprehensive review conducted by Banning (2004) discovered theories behind non-concordant behaviour, including that patients have a tendency to adjust their medicines in relation to how well they feel and other socio-cultural, behavioural and financial reasons. Older people are given limited information and education on their medicines so they often forget to take them, or take too many. It is now recognised at a policy level, that GPs and

pharmacists must ensure that older people are provided with written instructions (in large print if needed) and a full explanation of how to take their medicines so that *'no older person is in receipt of medicines labelled "as directed"'* (DH 2001). Social and personal factors affect medicine compliance and concordance, including poor vision, dexterity and confusion. To discover if this is the case, questions must be asked during medication review to ascertain if the patient is taking their medicines and support offered.

Tablets: packaging, preferences and price

Packaging, the type of tablet and the cost to the Government also create boundaries that affect medication management in older people. In primary care it is common for patients to have their medication changed to improve the cost-effectiveness of prescribing (Thompson *et al* 2006). However, there is a lack of information within the literature on how well patients accept these changes. Thompson *et al*'s (2006) study employed a postal survey to evaluate patients' experiences of switching medication, acceptability of the change, communication and packaging. They discovered that 91% of patients reported experiencing no problems following the change in medication. However, they did not focus on tablet medicines within a specific population or investigate the nature of the changes.

It is concerning that almost two thirds of patients questioned in the Thompson *et al* (2006) study did not feel that they had the opportunity to discuss their medication changes and some of the respondents felt that their views would not affect the outcome, as the change was 'inevitable'. These authors also discovered that older people found it challenging to cope with changing appearance especially when these concerned colour, shape and packaging (Thompson *et al* 2006). Kippen *et al* (2005) discovered that packaging was often not 'user friendly' and prescribing was *'sometimes done in a way that could create waste and confusion'*.

Overgaard *et al* (2001) carried out a study in which patients were asked to swallow different sized tablets with different surfaces and visually assess the shape and colour of tablets. The results showed that gelatine capsules were easier to swallow than tablets, coated tablets were easier to swallow than uncoated normal tablets, the preferred colour was white for both capsules and

tablets, the most disliked colours were purple and brown, the preferred shape was arched circular for small tablets, oval for medium sized and big tablets and the difficulty to swallow tablets increased with increasing size.

De Craen *et al* (1996) performed a systematic review to investigate the perceived effect of colour of drugs. They discovered that colours have universal meanings. In a wide variety of cultures, red is considered strong and active whereas blue and green are associated with good (Adams & Osgood 1973). The colour of drug formulations might cause different expectations in patients, and could therefore produce different therapeutic effects. The results showed that red, orange and yellow tablets are best for stimulant drugs and blue and green tablets are best for sedative drugs. It was also found that red, yellow and orange are related to stimulant effect whilst blue and green are associated with tranquillising effect.

Colorcon Inc. is a company that produces '*patient-friendly tablets that are easy to identify and swallow*'. Colorcon Inc. sponsored a survey to discover whether distinctive tablet appearance reduces dispensing and patient medication errors (Primezone 2006). This survey found that medication errors were reduced by tablets with distinctive colours and shape (Primezone 2006). They found that differentiating between tablets was difficult, especially when tablets and capsules are removed from their original packaging.

Drugs need to be 'patient-friendly' to improve medication management in older people. Consideration must be made for older patients, who may struggle to comply with medicine regimes due to difficulties swallowing large tablets and accessing 'child-resistant' packaging. Furthermore, many older people have difficulty accepting changes in tablet colour, shape and packaging. For others, changes in appearance can actually be an important safety factor. If a prescribing or dispensing error has been made then the changed appearance acts as a cue for the patient themselves to be alarmed and contact the pharmacist to check what has happened. If patients become blasé about changes in appearance then this safety factor disappears. Patients should be encouraged to query unexplained changes.

It has been suggested that the Department of Health will set out proposals in 2010 that would potentially disrupt people's self-

management of medicines approaches which in turn could affect adherence (Baker *et al* 2009). These proposals concern the implementation of 'automatic substitution' of some branded medicines for generic ones by pharmacists. Therefore the need to investigate people's perceptions of changed appearance of medications has never been more pressing.

Conclusion

Whilst much is written about compliance, concordance and medicines management, there is a great lack of evidence concerning changed appearance of medicines and effects of this on older people. This study seeks to address this gap by contributing research evidence on this issue.

PART 3

Study Design

Study aims:

In conjunction with study advisors, the aims of the study were agreed as being:

1. To design a qualitative study in partnership with older people to elicit older people's experiences in relation to changed medication appearance
2. To identify any impact on older people's personal approach to medication management as a result of changed medication appearance

This is a patient experience study as opposed to a study of pharmaceutical or prescribing practices. The intention of this report is to share patient's experiences of the topic under investigation so that others can seek ways to improve that experience in the future.

Older people's involvement:

Older people have prompted this study and have been involved as advisors since its outset. Rochdale User Carer Action Forum members have informed the study design also. The advisors have had an impact on the questions to be asked and wording of these as well as specifying the target population as being participants aged 60 years and above. Advisors were clear that the number of potential participants would be optimised by indicating that reply slips for further information should be returned to an Age Concern office rather than a University of Salford address as first proposed. Advisors provided access to the Rochdale User Carer Action Forum to gain first hand anecdotal accounts of older people to inform study design. As one of the Forum members is Chair of Age Concern Metro Rochdale this enabled the research team to link closely with this organisation. Individual advisors' own networks e.g. Pensioners' Association, Over 50s Group, permitted a wider reach to gain the views of older people to inform the study focus as well as providing direct access to audiences to disseminate findings to. Advisors helped design the postal survey of the same topic (Williamson *et al* 2009) which ran consecutively with this study.

Sampling:

The population for inclusion was all older people aged 60 years or over residing in Greater Manchester and currently prescribed three or more medicines in tablet / capsule form.

All 2000 participants in the related survey of the same topic (Williamson *et al* 2009) had invitations to request further information about being interviewed enclosed within their questionnaire packs. Over a hundred potential participants requested further information. Of these 32 people went on to volunteer to participate in in-depth face-to-face interviews.

Participant's ages ranged from 62 years to 88 years old with an average age of 72 years. There was a fairly even split between male and female participants with 17 being male and 15 being female. The number of types of tablet / capsule taken by participants ranged from 3 to 16 with the average being 6.

In this study the participants have been self-selecting from within the target group. This has implications for the study limitations (see page 20). The number of participants who engaged with the study is very satisfactory as it enabled an in-depth exploration of the population under study. The research team achieved rich and thick descriptions of the topic area and valuable insight into individual and common experiences. The number of participants was sufficient that a point of data saturation was reached whereby no new themes emerged from later interviews giving confidence in the findings.

Interview guide:

The interview guide comprised 9 questions developed with input from study advisors (see Appendix). The questions were further informed by the literature and findings from the previous postal survey focusing on the same topic (Williamson *et al* 2009). The questions were adjusted in the light of emerging findings and additional probes made to enquire about participant's views in relation to control, 'getting older' and confidence especially.

Data collection:

- **Procedure**

All former Primary Care Trusts (PCT) in Greater Manchester were invited to take part. Of the six that consented, all GP practices within them were sent a written invitation to assist in forwarding a questionnaire to patients who met the criteria for our previous postal survey study. From those six PCTs, a total of ten GP practices agreed to assist. The PCTs were Heywood, Middleton & Rochdale PCT; Stockport PCT; Ashton, Leigh & Wigan PCT; Oldham PCT; Salford PCT; and Tameside & Glossop PCT.

Each GP practice distributed 200 pre-packed survey envelopes and enclosed within each was an invite to take part in this further qualitative study of the same topic. Thus study participants self-selected from those who were sent a questionnaire.

On receipt of reply slips requesting further information, each potential participant was sent a study information sheet and a further reply slip in relation to being contacted to discuss and arrange an interview. Interviews were then set up at a time and place to suit participants. Data collection took place in summer 2009.

Semi-structured interviews were the data collection method of choice. These permitted a conversational-style of interviewing which helped put participants at ease and encouraged them to share their experiences and views openly. Such an approach was considered to be the best medium to develop an understanding of the possible impact of medication appearance changes on individual older people.

All participants except for 2 men were interviewed in their own home. The two men who opted to be interviewed at the University of Salford explained that they liked to get out of the house. Twenty-nine interviews were conducted totalling 32 participants. Three of the interviews involved both the husband and wife. All the interviews were digitally voice recorded and just under half (14 participants) were video recorded. Of these, only 4 were women. The interviews lasted from between 10 and 43 minutes. All the interviews were transcribed verbatim.

- **Use of video / audio recordings**

Participants that consented to be videoed were made aware of the intended use of the video data, the impact on confidentiality and the lack of anonymity. Nearly all the participants however, were not concerned about confidentiality and said would have been happy if their original names were used. Digital images of the medications participants shared with the interviewer were taken where video was not being used. The digital images helped capture the participant's descriptions of the medication appearance changes and provide a useful visual representation of the problems and concerns which the participants raised. Recording equipment was small in size and positioned discreetly to avoid being a physical barrier to the interview process.

Data analysis:

As is common practice, the interviewer maintained 'analytical memos' (Bailey 1997). These provided a means of reflecting on and verifying emerging themes and concepts with data from other interviews and in interviews with further participants. This helped promote confidence that the emerging findings were an accurate reflection of participant's views and meanings and not those of the interviewer. This was especially important as the authors' previous study (Williamson *et al* 2009) had uncovered significant problems for many older people who had experienced changed appearance of medications. Findings were further validated independently by a second member of the research team who examined all the study data.

The interviews were analysed using a constant comparative analysis based on a theoretical sampling approach (Corbin & Strauss 2008). This meant that the iterative nature of the interviews enabled the emergence of early themes which were then explored in greater detail to discern the key concepts within them. These concepts were then sampled further as the interviews progressed until the themes and concepts were saturated – that is, no more concepts emerged and the themes were consolidated within categories and one core category.

Ethical considerations:

- **Approvals**

The study received approval from Ashton, Wigan and Leigh Local Research Ethics Committee and The University of Salford's Research Governance and Ethics Committee. Research governance approval was gained from ReGrouP based at the former Salford PCT. Study design was informed by the Patient Information Advisory Group (Department of Health) such that approval was not required from it.

- **Issues**

Whilst use of video recording equipment is not novel in interviewing situations, it is little used in comparison with audio recording. The value of seeing participants sharing their views and showing their medications was considered a valuable element to the study. The older people who acted as study advisors felt use of video was very appropriate and advised that many participants would be more than willing to be filmed. The Study Advisory Group agreed that findings would likely have more impact if using video clips in presentations of findings rather than sole use of anonymised quotes extracted from interview transcripts. Both the study information sheet and explanation by the interviewer clarified issues about confidentiality and lack of anonymity to ensure participants knew what they were consenting to. Participants gave written consent for their video clip to be used in study presentations. Participant names have been replaced by pseudonyms within this report.

The study information sheet made clear that participant's GP or pharmacist would only be contacted with permission should any participant be found to be at risk by their medicines management. The interviewer is a Registered Nurse and did on one occasion have reason to contact a relative of a participant to arrange GP contact regarding extremely unsafe medication practices with their permission.

Study limitations:

It has not been possible within this study to drill down to ascertain causes of changed appearance of medicines. They can reasonably be expected to be largely due to generic prescribing

practices but it is acknowledged that reported changes in appearance may have been due to other causes such as dose changes. The study relied on participant's recollections of changes in their medication appearance which may not have been entirely accurate. An alternative approach may be to examine what medicines are dispensed and the actual reasons for any changes in their appearance by speaking to the community pharmacist who dispensed them.

The study was not sufficiently funded to send repeat letters of invite as is common practice to maximise recruitment. It was felt other measures such as the return address being an Age Concern office, went some way to address this issue.

As a largely self-selecting sample, the views of those participants who chose not to participate may well be considerably different from those that did. In particular it is acknowledged that those who did not feel they were managing their medications well may have wished to avoid declaring this at interview. Conversely those who felt they had no problems at all may also not have taken part. Anyone lacking competence or capacity to manage their medications effectively may well have been less able to take part in the study, thus the self-selecting sample has been opportunistic. A bias to participants who are both competent and who have capacity in managing their medicines was evident. Interestingly, nearly all of the participants remarked on how appearance changes in medications could be a problem for 'older people', that is people that are older than themselves. A different sampling approach would be needed to locate any other populations of interest such as more vulnerable or at risk participants who are perhaps more likely to experience negative effects from changed appearance of medications.

Any further study could also usefully identify and quantify those who did not have any problems with their medicines appearance, and those who have had such a problem that had been solved by discussion with a healthcare professional (e.g. their community pharmacist).

PART 4

Findings

After careful analysis, three categories and one core category emerged from the data. These are 'the importance of routine', 'confidence', 'being old' and a core category of 'retaining control'. The categories illustrate the concerns raised by participants surrounding the impact of changes in medication appearance on their medicines management. The categories highlight the need for maintaining routine and the impact of appearance changes on confidence at a personal level, in others and with the medications themselves. Participant's shared perceptions about 'being old' and how these influenced their management of the appearance changes are presented. The core category of 'retaining' control is reflected throughout all other categories and illustrates how participants seek to maintain stability with their medicines management through such measures as avoidance of changes in appearance or by adapting to change through information.

The importance of routine:

The importance of routine formed the first category of these findings. In nearly all the cases ($n=29$) the participants had a regimented routine which they maintained despite any medication changes. Their routine was the bedrock of their medication management and provided a 'security blanket' which they used to help remain in control of their tablets. Any change to medication appearance threatened this position and prompted participants to reassess their medications and question or double check their routine. Thus the impact of the appearance changes varied. From the outset, it became evident that although the participants generally felt that they had little or no actual problems as a result of the changes, they had impacted on their daily medication administration in a number of ways. Many had to double check their tablets and some felt the need to contact the pharmacist or GP about them whilst a number of participants questioned the rationale for the changes. Their main concerns related to colour change. Some felt that the size, accessibility of packaging and naming of the tablets was frustrating. Generally, the participants said that they managed the changes satisfactorily but were clearly tired of keeping up with the frequency of the changes they experienced.

This point is illustrated by the following participants:

“If you have a routine and you carry out the same routine every Monday morning, I don’t see the problem. I know that I take five tablets, plus my Aspirin. I get five lots of seven tablets out and I don’t see that there is any confusion and then every morning I take all the seven packs of tablets out, use them and put them back in.” (Andrew)

“Yes I have a system and so I know what I’ve ordered and I just make sure that what I’ve ordered is what I get.” (Jim)

“Well, it is very easy to get confused as you get older and I only take my tablets twice a day, morning and night, so at night time I put the tablets out for the night and for the morning.

Okay.

I take my night time tablets when I go to bed and then the others I take when I get up in the morning.” (Dylis)

Whilst these quotes are from but a few participants, there were many instances where participants referred to their routine. In all cases, the participants demonstrated how they managed their tablets through complex administration systems, through to simple cardboard boxes and counting out morning, afternoon and evening tablets. The range of routines displayed throughout the project was extensive and many participants prided themselves on their control and organisation of their medication. As can be expected, those with more medications to take than others found appearance changes more challenging. Overall the routines developed by the participants demonstrate how they coped with the appearance challenges and retained control of their medication.

- **Managing appearance changes**

Changes in colour

Changes in medication colour were by far the most common changes noted by the participants. Although many did not refer to these as major problems they did confess that these changes

cause some concern. Interestingly, colour was viewed as a particularly important factor in the management and control of self-administered medication. For many, colour was used to denote a particular tablet – for example, some participants referred to “I take the blue one first and then the pink”.

To further illustrate this point, Joyce and Pete remarked on how Joyce uses the colour to denote which medicine she is taking:

“Well I do, look I am aware of what I’m taking, I know that the evening one is pink and the two ones in the morning are white.” (Joyce)

A further participant explains their preference for consistency in colouring:

“Again, when the colour changes, or if there is any other change in the medication, I always check the packet to see whether I am actually getting what I am prescribed, whether they are 20 mg or not. They always are, but it would be better I think if a 20 mg tablet had a standard colour throughout, irrespective of size or shape.” (Henry)

Whilst not problematic for him, John explains why colour change is a concern:

“Just pure familiarity. You get them out and you think right it’s 2 of those, 1 of these, one’s a big pink one, the other’s a blue one or whatever it is, and you just get used to that particular range of order of things, and when they change the colour... I mean alright it doesn’t really throw you but familiarity when you’ve been taking them for a long time and you think oh dear what’s happened here.”

In other cases, participant’s tablets *all* changed to a single colour such as white, which made it difficult to discern between the tablets. This was particularly problematic for those participants who dispensed their own tablets into a Dosette box (see Figure 1). Figure 1 shows Jo who is a 78 year old lady who expressed some concerns with the changes in the colour of her tablets. Jo was fiercely independent and managed her tablets well. Every week, Jo

would dispense her medication into a Dosette box which was an unremarkable event until the colours changed. At the time of interview all of Jo's tablets were white and Jo was having difficulty in identifying them and also struggled if she accidentally dropped one on the floor. With all the tablets being white – it is difficult for her to discern which one she has dropped:

“They all seem to be the same colour these days, which is quite confusing, when you come to put them out, because if you just lose track of what you are doing, and you’ve got all the white pills in the box, I can’t see the numbers on them now...” (Jo)

Jo's complaint about similar colours was not an isolated incident, many of the participants felt that the commonly experienced change to all-white led to some confusion and made self-administration problematic.

Figure 1:



In some cases, the therapeutic actions of the drug were questioned when the colour changed. For example, although participants didn't normally question the efficacy of the drugs, they did comment on whether the drug was actually doing the same work. Trevor and Sarah talked about their concerns when a capsule that Trevor had been taking for a number of years suddenly changed colour:

“Oh yes, because they sent capsules instead of tablets last month didn't they? (Sarah)

Yes, they did. (Trevor)

I got on the phone right away. (Sarah)

You see one of the things on there are meant to be capsules, they are meant to be capsules because of the time release, I mean capsules have a different time release to a tablet and they should be a coated tablet and what we ordered is tablets and they sent capsules. So we had to phone them up. They haven't got the tablets so they sent the capsules which are wrong really but they said they were the same time release, but even they were a different colour. The capsules they sent were an all white colour, whereas the normal ones we get are a two-tone colour, kind of a brown and a sandy colour.” (Trevor)

Although most participants remarked that they managed colour transitions satisfactorily, some had taken the wrong tablet or were convinced that they had made a mistake. Glenda's experience of taking the wrong tablet as a result of the change in colour exemplifies this and highlights the potential hazards presented by medication appearance changes:

“I have had my medication mixed up with my husband's and I've ended up taking his instead of mine, because they both look the same.

Oh right. Really? Could you tell me a bit about that then?

Yes, well mine are for blood pressure and his are for prostate problems, and one particular time when my medication had just changed colour and shape, I saw his on the table, thought I hadn't taken mine and I took his.

Because in the morning... I mean during the week it doesn't matter because we both take them when we get up which is at different times, but at weekends we get up at the same time and we have our breakfast together, and we both take our tablets with the breakfast, so they are out on the table, his and

mine are out on the table, I'd already taken mine then see this tablet on the table and thought oh I must have forgotten to take that, and took his as well. And it only came to light when he said where's my tablet gone?" (Glenda)

Changes in shape

With nearly all of the participants ($n=29$), a good routine was essential in order to maintain their medicines management. Dot talked about her use of shape to denote when she took her tablets, and comments on how change in the shape can affect her routine:

"Only in the fact that like in the morning, I'll have 3 oblong and 4 round, and if they change then I might have reversed." (Dot)

This was also highlighted by Trevor and Sarah when they discussed the length of time they had both been on medication and how they had become familiar with their own and each other's tablets:

"We've been getting them now for 20 odd years, so we are fairly well familiar with what we are looking for and I order them, you see." (Trevor)

Many participants experienced multiple medication appearance changes and Dot experienced 6 changes in one month and 5 in the month following that:

"Well sometimes they are very small and round, they are all different ones, sometimes they are lozenge shaped, sometimes they are oval, sometimes they're small, sometimes they're large, sometimes they have writing on, sometimes they don't, so you never know from one month to the next what they are going to be."

Changes in packaging

Whilst the focus of this study is on appearance of medications themselves, some participants raised changes in appearance of packaging as an issue. Some packets changed to have similar

colours and shape to others which again made it difficult for the participants to discern one medication from another (Figure 2).

Overall, any appearance changes resulted in participants having to double check their medications and the instruction leaflets. Although most were happy to do this, there was an air of resentment at having to repeatedly check the medications when they had changed. Familiarity with tablets distorted when tablets changed appearance significantly (see Figure 3) which caused some participants loss of confidence in their routine and medicines management. The importance of self-medication and control here is evident because participants consistently remarked how they could manage but only because they had become used to the changes and just got on with self-administration.

Figure 2:



Figure 3:



One suggestion was that a written note be developed to accompany dispensed medications:

“I’m wondering whether there ought to be something given out by the NHS, to shall we say to the over 65’s or the over 60’s. That explains all that we have been talking about, in simple terms. There may be changes in the colour of your tablets, this could be... and then whatever reasons there are. Just a general, I call it a reassurance, not a frightening thing, something that might just reassure people that if they do find there’s a change in their medication that the doctors or the hospital ensures that they are being given the best...”

Yes.

...medicine to help their condition, or whatever. You know looking at it perhaps as something that maybe might help older people. And obviously those that can't read, somebody will read it to them, the chemist or the pharmacist would say well can you make sure that your patient, the carer or whatever, there would be a way that they could perhaps make sure that everybody needn't be frightened or upset or concerned that there was a change in the tablets.

Yes.

And that if they did have any concerns, please don't hesitate to speak to your health worker, your carer, your doctor, the NHS, your whatever.

Yes.

That's a way I think that might just help to reassure people. I don't think it would cost all that much."
(Marge)

- **Managing access**

In some cases, participants reported difficulty in physically accessing their tablets due to a change in the cover of the tablets. For those participants with arthritic thumbs access to some tablets was especially difficult. David talked about his frustration when the packaging of the tablets changed. For him, the change from a 'pop out' foil covered sheet to a 'peel back' packaging caused some problems and upset his medication routine. Figure 4 illustrates this change and the following extract provides an example of this concern:

"... it has changed the box, but it's the... these are fine, I've no problem with it, this type.

Yes.

But for some reason, they changed the foil pop-ups into a different thing where you don't... this one you

just press and it pops up, no problem, because they are only a small capsule, but they brought another one out where you had to peel the corner...

Oh right.

...and peel it off. I take these the early hours of the morning, so I go into a routine, I don't like my life being controlled by tablets.

Yes.

*I like to be able to do a full day's work or whatever I'm going to do, without having to stop to take tablets, so I've got them the early hours in the morning, first thing in the morning, and last thing at night, which is better. With taking them the early hours of the morning, I'm fiddling about, and then my wife will wake up, give me those bloody tablets, and she'd have a fiddle and then you'd peel it off and it always broke off, you had that much messing about because it's only a tiny capsule inside there, it would squash and then you'd drop it on the floor and you couldn't find it, it was awful, and I did complain to Boots Chemist because it's quite a good one up at ****, and whether that had anything to do with it, anyway they went back to these and these are fine.” (David)*

Figure 4:



Similar concerns were raised by other participants and on the whole, although they had some difficulty accessing the tablets, they developed ways of managing change. Dot provided an example of this where she stated that she struggled to open Aspirin:

"It is so hard to get out the majority of Aspirin, in fact my sister said oh I forgot I was going to be bringing you... I've never heard of them... a pill pusher to get them out because I've got arthritis in my thumbs. These are quite ok, that's easy but some of them are really hard, they're round... if it's a square packet the round ones... are sometimes... that's one there... I've had to ask my husband to get them out because I could not physically push them out for some reason.

Yes.

But I don't know what make it is that does it, I don't know whether it was that particular one, but it's that shape, you just can't get them out of the blister pack, they won't push out for some reason, but the others I don't have any problem with any of the others, it's always Aspirin. (Dot)

Size as an issue

Whilst size did not get raised as a particular issue in relation to appearance, it was brought up in relation to accessing tablets from their packaging. Some participants felt frustrated by the changes they had to make to accommodate the size change with some tablets. Some size changes meant that they were now more difficult to get out of the packets. This was especially pertinent for Aspirin because the size became smaller. Equally, some tablets in foil packaging such as Omeprazole were hard to get out of the packets. Other tablets simply snapped in half when the participants pressed against the foil to release the tablet. With most participants, changes in the size didn't really matter. Most reported that there had been changes in the size of the medication but that this hadn't really caused any problems. However, one participant, Henry, had some problems swallowing the tablets following a change in size. Henry had gone so far as to measure the tablet

difference and commented that he wasn't consulted about the change and now found it difficult to swallow the tablets:

"The 20 mg Enalapril Maleate tablets vary considerably in size from approximately 44.2 sq mm for the Karib Kemi, and Pharmagreen, to approximately 78.5 sq mm for the Dexcel-Pharma product. The latter are also much thicker and some patients might have difficulty in swallowing them."
(Henry)

For Henry, this meant some loss of control over his medications management which he was frustrated by. The following conversation illustrates this point:

"Have you had any problems swallowing them?"

Yes I've had a little bit of a problem, sometimes it doesn't go down the first time.

Is that because they've got bigger or because they are smaller because some people...?

Because it's bigger.

... so the bigger tablets you have trouble swallowing, sometimes?

Yes, they are... I'll show you one because we're going to photograph it anyway, they are scored on one side so you can break them.

Yes.

Personally, I would prefer a small tablet than a thing like that. I've never broken them, I've always managed to swallow them...

Yes.

... but I would much prefer the smaller tablet and I'm rather puzzled why there is... it's such a dramatic

difference in size, because not only are they much bigger in diameter but they are also quite a bit thicker than the smaller ones.” (Henry)

Other participants questioned why the size changed but commented that it didn't affect their routine or cause any problems with swallowing. For some, however, the changed size caused them to question the efficacy of the medication and lose confidence.

Overall, changes in participant's ability to access tablets were due to altered packaging or altered tablet size. Most reported problems related to tablets breaking or being dropped as too small and fiddly to handle. Most participants were able to embrace the changes within their medicines management routines and actual problems with accessibility were expressed by only a few participants.

Confidence:

Issues relating to confidence amongst participants formed the second category of the study findings. Confidence became a significant category and was broken down into three sub categories: confidence in self; confidence in others such as health professionals and confidence in the medications themselves.

- **Confidence in self**

Over the duration of the study, it became apparent that the participants needed to be confident in a range of areas. The frequent changes in medication appearance hampered their confidence that they had previously formed through their medicines management routine, knowledge of medication and confidence in health professionals. For some, loss of confidence also extended to their beliefs about the quality and effectiveness of a drug. These different sources of reduced confidence compounded to reduce self-confidence generally.

- **Confidence in others**

For the vast majority of participants, any medication changes could be readily checked with the pharmacist or the GP. Most of the participants felt confident in contacting their GP or pharmacists for advice. The helpfulness of pharmacists in relation to responding to queries was strongly evident across most of the interviews. Some

participants did not check any changes with health care professionals because they had faith in their GP and were confident that the tablet content would be the same.

Terry stated that he had never queried the tablets he was on because he believed in the GP and pharmacists and trusted their professional opinion completely:

“Okay. Did you ever query why the packaging had changed?”

No I just assumed... you see to be honest with you I’ve got a very, very good doctor...

Yes.

... and the pharmacist, she’s absolutely brilliant, so you know I’ve every confidence... it’s just commonsense if you look, you can see it’s the same product, it’s just that the packaging has changed.

Okay, did you ever query whether or not the quality had altered, or...

No.

No. So you just thought you were getting the same.

No it’s like I said, I’ve got every confidence in my doctor and in my pharmacist.” (Terry)

This faith in the health care system was strongly evident in all of the interviews and many participants did not want to be seen as ‘complaining’. However, they did feel that if there were any changes, then these were adequately managed by themselves through initialising contact with their GP or pharmacist:

“For some reason it’s just a different colour and I’ve not realised until I’ve got home and I phoned the chemist and they reassured me.” (Michael).

Some participants suggested that not everyone would find checking their medications easy to do by going back to the pharmacy or by telephone:

“So the question is, are they both the same? And you say do you phone the chemist? Well I know people who don’t have a telephone or don’t wish to use a telephone. We’ve got several friends... we’ve a lady who’ll come down here with all her tablets and say to me are these the same and should I be taking them?” (Trevor & Sarah)

Others stated that their medications had often changed as a result of attending a different pharmacy. In these cases, the tablets changed depending on what type the differing pharmacies dispensed. This caused some of the participants to go elsewhere for their medication although most were happy with the pharmacists and continued with the same pharmacy.

Whilst health professional staff were highly regarded, one participant Michael (71 years of age) felt that they needed to improve communications with people and especially older people. In Michael’s view, a lack of information resulted in confusion – which he believed was predicated by the lack of time spent with patients. The following excerpt explains this:

“... and actually they get on the minibus and they are asking me, and I say no you must ask your doctor to be... but I got the impression when I was in hospital the staff were overworked, they didn’t have time to speak to patients, and explain properly what treatment, what medication, and even myself, three months after I came out of hospital, I was ok, I had an appointment to see the surgeon and I asked him then, three months after, what I’d gone through. Alright possibly I wasn’t physically fit enough to do it when I was in the hospital but I do see a lot of... I come across a lot of people who do seem confused with treatment, medication and everything, but I put that purely down to unfortunately lack of personnel in the hospital which is all down to costs of course.” (Michael)

Only one participant stated that they had been contacted prior to a change in medication appearance although many did suggest that information provision and being alerted to any changes would have been useful and allayed some of their initial anxieties. Michael illustrates this point best when he was asked why he thinks tablets change appearance:

“Well being a bit suspicious, I was thinking possibly cost, is it a cheaper...”

Right. And how does that make you feel?

I don’t know. I think it always makes you feel a little concerned, I appreciate that the costs of the National Health is horrendous but I think I would have preferred it if the chemist had approached me and pre-warned me...” (Michael)

- **Confidence in medications**

On the most part participants recognised a need for the NHS to reduce costs and manage its pharmacy services cost-effectively and this helped them to accept any medication appearance change. Some participants ($n=8$) however questioned the quality of the medication and felt that reduced cost meant that the tablets may not be as effective. Whilst this didn’t deter these participants from taking the medications it did reduce their confidence in them and two participants stated that they had noticed a change in the effect of their tablets. Confidence with the tablets was implied in nearly all of the interviews and was seemingly underpinned by participant’s familiarity with the tablets they were taking. Thus any changes to the tablet affected this confidence. Jaunty summed this up in his conversation in which he remarked on the frustration and anxiety he felt when his tablets changed:

“As soon as I lost that little bit of confidence that was it. That’s the magic word behind this, and it’s the magic word behind any changes or differences in medication, it’s undermining the person’s confidence and I think that’s... right deep down. That’s a word perhaps you haven’t thought about. I might be wrong there. Confidence is a very, very important part of life’s structure, and its part of our daily routine. Its

part of what you're doing now, talking to me. Life is all about confidence. You look outside and you think it's a lovely day to day, isn't it? And the reason you say that is because you want somebody to agree with you.

Yes.

And when somebody comes along and puts a different coloured tablet into a packet, the first thing is what's happening? Why have they done that? Your confidence at that moment is put in question. That change after 30 odd years or so of that type of inhaler, it was like somebody dangling the rope when you're ready to fall into the water, and you think you're going to miss that rope. It's a lifeline, and that lifeline is the word 'confidence'. Think about that and that will answer a lot of the problems that people have I think with their tablets, underneath it all, it's an underlying stream.” (Jaunty)

Changes in some participant's medications had made accessing and managing them difficult and some had recently changed to a Dosette system managed by their pharmacist. Bernadette shared her experience of this as she had found it difficult to keep up with the changes:

“... it's so very hard to take the tablets today because they're all different makes and they are all different companies that make them and some of them don't feel as good as the old ones, and I find it very hard... I've got a pack all ready in the other room, to get them out, because I've got arthritis in both hands, and I struggle to get the tablets out of the little packets, but now I've got a cassette, have you seen the cassette?” (Bernadette)

For some, using a Dosette meant that they were reassured that they received the correct medication despite the changes in tablet. However, using a Dosette was not without its problems, as Bob illustrates. His tablets are now dispensed for him in a weekly Dosette, but he still observes the medication appearance changes:

“Sometimes they come in what I call rugby-ball shaped. And likewise, one of the tablets I get varies in colour from time to time. It’s orange and brown at the moment. Sometimes it comes as pink and grey, and that caused me... the first time it happened, to query whether I had got the right tablet.” (Bob)

Bob did on occasions question these changes with health professionals (GP staff member that deals with prescriptions and a pharmacist), but after a while, he became frustrated with the process and requested that a supplementary information sheet be provided with the Dosette. For Bob and many others, being armed with relevant information about the changes and the actual tablets provided some element of control. Participants were often reassured by the supplementary information sheets and referred to them on many occasions to double check the changes. Over the duration of the project, a number of participants remarked on how they initially relied on the supplementary information sheet to determine the accuracy of the medication. For others, the information sheet was then only used to check the accuracy of the medication when changes in appearance had been made. However the frequency of the appearance changes meant that for some, they no longer used the supplementary information sheet – they had merely ‘got used to’ the changes and were familiar with the different colours and brands.

These supplementary information sheets were especially helpful when Dosette box labelling had errors on them which was a frequent problem for Bob:

“The actual quantities label doesn’t... I think it might be better to put it... it would appear that there are errors on the label relating to the quantity of tablets contained in the tray.

Right okay.

Because basically the quantity of tablets has always been correct in number but the labelling hasn’t and this is what the medics at Rochdale Infirmary were quite concerned about. He said that these two instances here are quite simple to solve but you know if it’s repeated elsewhere it can cause

problems, that down there it says within a week you should have 10 but effectively you are not having 10, you are having 14 and you've got 14 tablets.

Can I just put that to the camera so that they can see the labelling? That's the new one.

That's the new one yes.

So along the top it's got Isosorbide Mononitrite 60 mg, then the number 14, but that doesn't reflect the number of tablets that are actually in ...

That is correct that one. It's the Metformin which is the error.

So the Metformin is 28 Metformin 500 mg tablets but there's not 28 tablets ...

Well to me the specification of taking 2 tablets 3 times a day, you require 42 tablets and a full box does contain 42 tablets but it's printed 28.

Okay.

The exercise repeats itself on Nicorandil."

George talked about how the changes in medication have caused some anxiety which resulted in him believing that he had taken the wrong tablets. The following excerpt taken from George's interview illustrates how change in a routine through medication appearance changes can result in loss of control and anxiety:

"Because sometimes... the other week I was... I'd sorted my tablets out like, I'd got them from the thing and I was sorting them out in their boxes you know as a thingy, because the morning ones I have up there and in there and then the afternoon ones are up there just the same, but I know where I'm working, you know what I mean?

Yes.

And I come to sort them out and I thought there's some tablets missing here, so I shot back to the thingy like, to the pharmacy, and I said I haven't got these tablets and I'd shown them the box which you know thingy and he said well where's your packet? Where's your thingy? I said it's here, you know it's a carrier bag full. So he goes in and he says they are them Mr X and there was a different type, you know a different firm and everything altogether.

Right, so you thought that you hadn't got them?

I thought I hadn't got them, you know.

Right, okay. So what happened?

Caused me a problem, yes.

Yes. But did that happen the once, or has that happened a [overtalking]

It has happened a couple of times, it has happened a couple of times, you know, but once he'd explained to me, I let it go you know what I mean? I didn't go, didn't go keep dashing back because I just thought oh well and then I came to look at the tablets then and I read them again and I thought oh well, these are the tablets I want you know, but they were just in a different box and a different... with different like, you know.

Originally, you did check this out with your chemist and realised that they were the same tablets?

Yes, he did turn round, you know, I went and I was annoyed you see, I thought, I've given my prescription and they put them all in a carrier bag which they put them in you see, and I thought I've not got them. I felt a fool myself when I'd gone and then when he showed them me you know, but same

as I said to him, well them's not the same box and same place as what I normally get.” (George)

George managed to resolve this problem with his pharmacist but later on in the interview he confessed that he didn't trust the effects of the tablets any more:

“My tablets made by the Co-op and then water tablets made by somebody else, well I always think the Co-op tablets are crap, cheap.

Right.

But they are doing it, they work, but they don't work as good as the next lot that comes up.

Right, so do you talk about this to your chemist, or your doctor?

No, I tell you when I noticed it sweetheart, I get it from the pharmacy up here, but now and again when the wife was alive, we used to go, when we go shopping down at Asda, I used to drop them off at the Asda pharmacy, you know what I mean?

Yes.

And the tablet was from a different firm and I'm being honest with you, you could really feel the difference of them ...

Right.

When you had them.

So what symptoms would you experience with the feeling a difference?

Well, I felt... when I got them from Asda, I felt a bit better, you know, I felt as though they was working proper and now here, so as I say, they are working but I don't think they were working as what they was with the tablet I get down at... It might sound, you

might think I'm sounding daft, but when I get them from Asda you know, but I don't get them from Asda now, because I don't go into Asda." (George)

Other participants, such as Jane and Mike suggested that the changes in medication were as a result of cost cutting, most accepted this as a rationale:

"No, it just seems to be which country they're sourced from, basically, and I can only assume that the tablets they are exactly the same because they're produced under licence but I can imagine some people being very concerned about it because they think well I always take a pink one, that's not a pink one, I'm not taking it, you know, and that can have implications on their healthcare. I mean if it says what it is on the label I have to believe it. Particularly when it's got the instructions inside, but it's only in the last few years this has been happening, I suppose it's cutting down costs for the health service, basically." (Mike)

The majority of the participants were content with the rationale for the change in tablets and were strong advocates of the NHS whilst several such as George expressed concern about the quality of the medication.

It could be expected that loss of confidence would have been helped by adequate supplementary information about medication changes being issued prior to any change. In only one case however, was a participant informed of an impending change. In all other cases, participants collected their usual prescriptions and were not informed of any changes. In these instances participants relied on standard instruction leaflets enclosed in the medication packaging against which they checked their tablets. Andrew was familiar with his tablets and used to read the instruction leaflets, but now felt confident in what he was taking so relied on them less. However, he still felt that it was important to include the instruction leaflets as this was a source of reassurance:

"I've read the information leaflet a long, long time ago, but I haven't re-read them for... unless... the

only new tablets I'm on are these and I'm on these for 12 months. I finish these in March next year, so I read the information leaflet on those.” (Andrew).

“Obviously it [instruction leaflet] is important because it is there for a reason and the reason is to reassure people, but when I have been taking tablets for as long as I have, I'm not really after the reassurance. The only trouble with the leaflets are, they are very ambiguous you know, they give you that much information that you could wake up in the morning and think these tablets are affecting me. You know, if you've got an ache in the back of your leg, you know or... I'm only taking that out of context.” (Andrew)

However, for those who use pre-prepared Dosettes issued by their pharmacist, standard instruction leaflets that would normally accompany medication packaging are no longer provided which is frustrating for some. Bob talked about this in his interview:

“...but there's no instruction leaflet but we're told to read the instructions carefully before partaking of the medication and I have in fact suggested to the chemist it might be worthwhile once... because they take these tablets out of the boxes in which they arrive from the manufacturers, from the pharmaceutical suppliers, it might be worthwhile with these boxes giving a set of the leaflets. In other words, there's 10 different tablets in there, so if once... these are coming every 7 days in my case... some people I think they get them every fortnight, they're a longer tray but they are for fourteen days but mine are for some unknown reason... well I know why it's for 7 days... but if there was a leaflet given and they could keep that as a - for want of a better word - a booklet leaflet, at least the participant has got it if they ever want to look back at it.” (Bob)

Other participants who self-dispense into a weekly Dosette that they bought themselves retain the instruction leaflets just in case they are needed. JR highlighted this point when she discussed her

routine and management of her medications through the use of a Dosette:

“They sometimes change colour and it’s a bit difficult to denote which is which, but I’m clued up, in the sense that I always retain the instructions or the leaflet in the medication.” (JR)

For others such as Bob, the information sheet was not provided because the medication was administered via the Dosette system. For some, this meant that they were reliant on the pharmacists dispensing the correct medication which disempowered the participants to check for themselves. The following extract illustrates the concern this evokes:

“One of the concerns I’ve had at the back of my mind when this system started, and I still don’t like, I’ll be quite open with it, when you get medication in the standard system, nor this box system, each packet of medication had what I call an information leaflet with it, and consequently that information leaflet will give you certain examples, if, for arguments sake, if you’re taking aspirin you must not take this tablet or don’t take aspirin when you’re taking this tablet. In other words, cautionary advice.

Yes.

That leaflet also gave you other information regarding the taking of this medication. With this system, none of these leaflets appear. Now, alright, I consider myself to be reasonably well educated and I can cope with it but the fact is I can find out and if I wanted to find out more about Metformin I can get on the internet and get all the do’s and don’ts and why’s and wherefores. But putting myself in the position of other people and... I don’t want to be sounding socially problemed really... but some people may rely on that information but don’t get it when they get this box system. In other words, we’re always told to read the instructions carefully before partaking the tablets.” (Bob)

Table 1 highlights the most frequent problems encountered by the participants and also illustrates how many felt that the changes were not really a problem because of the way in which they checked their medication.

Table 1: Frequency of Concerns.

Concern	No. of participants	Comment
Not really a problem	25	Always checked with the pharmacist or info leaflet
'Older people' have a problem	23	Acting as advocate
Different pharmacist	2	Changed brands
Quality of the tablets	8	Quality 'vs' cost
Poor eyesight	2	Double checking the tablets
Affected routine	17	Familiarity, control
Similar colour packaging	7	Affected familiarity and routine
Access	9	Physical ability and packaging

Whilst not necessarily being experienced as problematic for many participants, medication appearance changes were a cause for concern. This appeared to relate to how people managed medication regimens and the potential loss of control through change. Table 2 illustrates the key areas of concern identified during analysis of the interview data.

Table 2: Appearance Changes & Impact - Summary Perspectives.

Size = S, Access = A, Colour = C, Packaging = P, Shape = SH, Brand Name = B

Pseudonym	Age	No. of Tablet types	Changes Noted	Summary of general concerns
Bernadette	73	11	Lots unsure	Quite disorientated and had recently had her medications dispensed into a Dosette via the pharmacists. Had become increasingly confused with the changes and had probably taken too many of one drug. Scared of side effects and used to get mixed up when the boxes changed.
Sally	85	7	C,S,SH	Disorientated at interview and tablets were on the floor. Was very unsure about her tablets – had also had a recent assessment by pharmacist which stated that she didn't really know what the tablets were for – yet nothing done about this. Ended up contacting daughter and pharmacist to highlight concerns and sally's lack of ability to self-administer the correct tablets. Sally wasn't going to take the new pink tablets because they used to be white and she didn't trust them. (NB Sally had recently had a bad fall)
Val	62	3	S,C,P,A	Weak eyes so had to constantly check the tablets. Some difficulty with access due to arthritic wrists. Older people may have a problem. Consistency of quality. Loss of confidence.
Rose	75	4	S,C,B,	Lack of information provided. Similar packaging was confusing. Concerned about the 'e numbers' in colours used for tablets.
JR	65	6	S,C,SH,B,P	Perturbed by the constant changes in colour. Didn't like them all being white because difficult to discern which one was which. Wanted to be in control of the tablets. Used colour to distinguish the tablets. Referred to other older people less able that may have problems.
Dyllis	78	3	C,P	Excellent GP wrote to her to say that the tablets would be changing. No problems but older people will have.
Glenda	63	3	S,SH,C,P	Got the same drug in a different colour and accidentally took her husband's tablet of the same colour. Wouldn't have made this mistake if the colour hadn't changed. Not really a problem at the minute but could be a problem when she gets older.
May	71	5	P	Had to double check with the information leaflet. Concerns about rationale, quality of the tablets.
Marge	74	5	No changes	Wanted to participate in study to defend older people who may have a problem especially those with blindness. Strongly believed that all people should be informed of any changes in the appearance of medications.
Dot	74	8	SH,S,P,C, A	Changes frequently and was annoyed. Caused her to store tables differently. Dispenses into Dosette so needs to be familiar with tablets. Not informed of changes. Change in shape resulted in problematic access.
Joyce & Pete	64 & 68	?	C,S	Don't really have a problem but suspect that older people may have some difficulties.

Jo	78	10	C,S,SH	Colour confusing because now all her tablets are white – problem dispensing into a Dosette. Believed she had a bad reaction to the change in co-proxamol. The changes affected the organisation and routine of self-administration.
Mike & Jane	77 & 66	9 5	C,BN,SH, P	Had recently converted to a Dosette because of all the changes in appearance. Although no problems felt that older people may suffer. Always checked their tablets.
Michael	71	5	C,S	The pharmacist reassured him that they were the same tablets. Trusted the GP and pharmacist and didn't query the quality of the medication. Would like to have been informed about the medication changes beforehand.
Henry	76	3	S,C,	Declared that he wasn't old. Was concerned mainly with the size because it caused some problems swallowing. Had measured the tablets. Older people may have a problem with the changes.
Bob	71	10	S,C	Contacted pharmacist to double check. Now dispensed in Dosette – but now doesn't have instruction sheets. Strength changed – 20mg tabs to 2x10mgs.
Andrew	64	7	S,C	No real problems – just had to double check – may be a problem for older people. Too much detail on the instruction leaflets.
John	77	4	C,SH,P,B	Having the tablets all the same colour was confusing - preferred different colours to differentiate. Use of instruction sheets important and also need for bigger writing on the packaging. Felt that this would be a problem for older people.
Trevor & Sarah	82 & 82	16 (Trevor)	S,SH,C,B, P	Said that older people could have a problem. Were familiar with changes thus alert to any new appearances. Questioned the quality of the tablets and felt that some would lose confidence in the medication. You wouldn't buy an orange cabbage!
Phil	67	10	P,C	All tablets now white – struggled to differentiate because they were all in a Dosette and sometimes the labels were misleading. Fearful for the future and his health and older less able people.
Roger	65	4	C,S,SH	Problems because the packaging and colours of the tablets are similar which causes some confusion. Asked the pharmacist why and was told about the different manufacturer and a cheaper make. The colour changes with the pharmacist so Roger now goes to a different pharmacy.
Jim	88	10	C,S,P	Mainly colour changes and had some concerns about the fact that they were all now too similar. Says that this could be a problem for older people. Realises that they are cheaper but hasn't lost confidence.
Tim	69	3	S,C	No written explanation of changes. Could be a problem for older people. Consistency of quality.
Terry	68	8	P,B	Stressed that he was alert to changes – but other older people may not be. Just checked the instruction leaflet
Charles	80	3	C,SH,P,A	Helpful if chemist informed him of the changes. Had some problems accessing some of the foil blister packs. Felt that the constant changes would become confusing if he were to start taking more tablets. Older people may have a problem as well.

David	79	5	P,A,B,	Could be a problem for older people. Liked to be in control of the tablets and not <i>vice versa</i>
Bill	63	3	S,C	Older people may suffer. Bill forgetful at times and had to double check the tablets.
George	78	12	C,S	Lost confidence in the quality – felt he was getting a cheaper and less effective version. Used information sheet when unsure. Older people may struggle.
Jaunty	63	6	SH,S,C	Not bothered about the changes but now that they are all similar it becomes difficult to discern one from the other. Started off the conversation with a statement of how he was angry at being identified as 'old' by the study.

Overall, whilst participants did feel some challenge to their self-confidence by changed appearance of medications, most embraced the changes as they were able to reassure themselves that their medications were correct. A strong trust of health professionals helped to foster confidence as did participant's willingness and ability to check changes with them. Anxiety which did exist was mostly expressed as concern for other older people and participant's own future should they become less capable of self-managing their medications.

Being 'Old':

A further category that arose was that of 'being old'. Participants were keen to share their views about control and management of their medications, but wanted also to highlight their concerns for themselves and others. Whilst for many, the repeated medication appearance changes were manageable, many harboured significant concerns that as their age progressed, they would likely experience a loss of physical ability that would eventually compromise their ability to manage their tablets. Phil (67 years of age) has a number of medical problems and started the interview by discussing the aging process and the effects he perceived on himself. Seeing this as a challenge meant that Phil had to re-consider how best to manage his medication:

"Well of course as the older you get, I take a goodly number, I take 10 pills in the morning, and you would have thought that it was the easiest thing of all, you get out of bed and I put my pills in my mouth, have a cup of tea and they're gone."

Yes.

My wife will sometimes say to me mid-morning, did you take your pills? Do you know, I can't remember...

Oh right.

... but I now keep my pills not just in the packaging but every week I put a week's worth of pills into a container.

Oh a Dosette.

So at eleven o'clock in the morning she says did you take them I can just go yes, Wednesday morning's are missing so I took them." (Phil)

Any future changes in medication appearance were therefore recognised as potentially detrimental to participant's progress and health. This concern was reflected by most of the participants. Whilst keen to refute any negative effects of older age currently, these participants acknowledged some sense of inevitability of loss of physical ability at a later date. This raises questions about how at risk people will be recognised and helped to manage medication changes.

Such was the strength of feeling about this that half way through data collection an additional question was included in the interview schedule. The question asked why the participant had volunteered to take part in the study given that many felt they were not 'old' and did not have any problems. Their answers revealed that they were fearful of their own ageing and also wanted to speak up for those less fortunate.

Marge is 74 years of age and worked with people who are blind. She participated in the study because she wanted to help 'older people' and those less able. Marge did take tablets herself and had noticed changes – but she stated that this wasn't a problem for her. She read out the following statement which she had prepared prior to interview to summarise her concerns about 'older' people:

"The pharmaceutical industry is a business, it makes money, costs and advertising governs success or

failure of tablets, medicine, prescribed or over the counter. Competition is fierce between major drug companies, i.e. sharing, borrowing etc. Doctors and hospitals hopefully buy the most effective drugs, with the least side effects, which means not necessarily the cheapest. It is inevitable that colour change, size and shape of tablets will change as research, new methods of production prove efficiency of tablets and medicine are also the cost.

Right.

So I think the change is inevitable and I think personally this is just a very personal view there are many, many elderly people who do not like change and they see it because it's not a criticism, they just are afraid of something that's different. I see it a lot with this blind group that I work with on Fridays.

Yes.

They sit in the same place, must have the same rigid routine and I do think that it does frighten a lot of elderly people, a change in tablets. But I don't think it's any different from the fashion industry, things change in there, colours change and it's no different to me the fact that a tablet changes colour at all."
(Marge)

Throughout the study, the participants highlighted the concept of old as being 'old fashioned'. For them, the ability to manage their tablets suggested that they were not old and whilst they accepted that the medication appearance changes caused some frustration, it didn't ruin *their* medication routines although it could impact on 'others'. John (77 years of age) expressed how he felt fine, but could imagine that others would probably have some problems:

"Everybody gets old except you and me, I'm still 30. Other people grow old but you don't and I know people that have either great difficulty in either reading, seeing, or whatever and they associate things by shape and colour.

Yes.

And I do know people, older women particularly, who have actually refused these things and taken them back and said they are not like the other ones I had last month and they are not the ones I'm normally used to.

Yes.

I don't find it confusing but I would certainly prefer them to remain at least the same colour.” (John)

For many, the mere fact that they had been invited into the study was interesting because they didn't define themselves as old. Jane (63 years of age) and Mike (77 years of age) discussed how older people would possibly be affected by the change in medication appearance – but personally, they were fine. Interestingly, at the start of this interview, they were not keen to voice their age.

The following extract highlights how they had noticed a change in the colour of one of the tablets – but felt that this wasn't a problem for *them*:

“I think one of mine, particularly one of my tablets that I have been taking for years and years, years, Half-Inderal LA, that one was always grey and pink, it's been that colour ever since I started it, now it can be grey and pink, it can be a turquoisey colour, or it can be clear in the capsules and you know my... it doesn't confuse me too much but my thoughts are that more elderly people would get very... even more confused and if their eyesight wasn't so good as well.” (Jane)

Nearly all the participants ($n=30$) suggested that older people weren't necessarily those who were chronologically old. Indeed, the 'oldest' participant in this study (88 years of age) suggested that he wasn't yet 'old' and was quite capable of managing his tablets. Jim provides an example of this when he talked about his friend who he considered to be 'old' – in fact, she was 2 years

younger than Jim, none-the-less, Jim saw her as confused and someone who had problems managing her medication. Despite this, he was conscious that this could happen to him:

“But I think it could happen to people who get a bit confused, I think, but at the moment fortunately I don’t get confused. That day will come probably.”
(Jim)

Throughout the study duration, not one person admitted to feeling or being ‘old’ and two of the participants were offended that they had been bracketed within this definition. Conversely, many others did not find the term ‘old’ offensive. Through the participant’s accounts, it became apparent that management of any changes in appearance of medications was an issue associated with physical and mental capacity rather than age.

JR (65 years of age) summed this up in her interview where she prided herself on her know-how and mental agility to dispense her own tablets into a Dosette. This meant that she didn’t have to rely on a pharmacist and so retained some control:

“No, I don’t have them done by a pharmacy because I’m not old and dodderly. I consider myself a fairly clued up woman...” (JR)

Overall, although it was generally accepted amongst the participants that the study was important they felt it was not necessarily directly relevant to them. Some participants were fearful of physical and mental degeneration and were aware of the effect that this could have on their self-administration of medication. This is one of the reasons why some of the participants chose to take part in the study, as advocate for ‘older people’; and future defenders of their own health and well being.

Retaining control:

Ultimately, the categories revealed a commonality amongst all of the participant’s stories. The ways in which the changes in medication appearance had potentially disempowered them was quite striking. Almost all of the participants prided themselves on their ability to manage and self-administer their medication and despite the appearance changes, they were able to do this

because of a good routine and physical and mental capacity. To some extent, they all remarked on how this helped them remain in control of their tablets, rather than the tablets controlling them. In some respects, being in control of their medications went some way to busting the myth that they were 'old' or that they could be classified as such in an ageist way. For them, 'old' was a derogatory word which meant decline and dependence.

Participant's methods for maintaining control echoed the ways they managed their tablets. All the regimens varied. Some kept their tablets in the original containers:

"If you have a routine and you carry out the same routine every Monday morning, I don't see the problem. I know that I take five tablets, plus my Aspirin. I get five lots of seven tablets out and I don't see that there is any confusion and then every morning I take all the seven packs of tablets out, use them and put them back in." (Andrew)

Some re-dispensed their medication into boxes, old margarine tub's, Dosette boxes and small coloured containers. Some had an array of tablets spilling out from an undersized cup or box. It was obvious that all the approaches worked sufficiently well for the individuals using them – despite the outward appearance of some of them being in a jumble. This was made possible because of the person's familiarity with the medication, confidence in the tablets, faith in the health professionals and subsequent control over the medications. Thus any changes were managed accordingly so that they did not disrupt the established routine. Whilst few known medication errors were divulged by this group of participants, the risk for these is evident in the way that participants tailored their medicines management. These bespoke storage, labelling and administration solutions may not be what health professionals would advocate not least as they introduce room for error such as when participants decanted tablets into unmarked containers. However, for participants, disruption of an established routine such as when medication appearance changes, similarly introduces opportunity for mistakes of varying severity.

One participant commented on the confusion presented by changed medication appearance:

“I think it’s confusing to change an appearance. I think if the tablets remain... whoever manufactures them... if they remain identical, shape or... because the shape changes sometimes on them, I think it wouldn’t be any problem.” (Jim)

Another believed her approach to managing medications worked well but then noted that was not always the case:

“... and I try and use a new blister pack if you follow me so each day I would take one out of each one so I could look at them and know that I’d taken the one...”

Right okay.

...because if there was 2 out of one and 1 out of the other I know I haven’t taken that one.

So you’ve got a routine that enables you to manage where you are up to with your tablets.

Yes I take 3 in the morning and a different one at night, so I separate them, only in my drawer, so the 3 are on the left hand side and the 1 is on the right hand side and I compare the missing tablets if you like just to make sure that I’ve had 1 at the right time.

Right, okay.

It doesn’t always work but it’s an aid to making sure I’ve taken them.” (Roger)

Overall, participants were keen to avoid being considered as ‘old’ and instead highlighted the issue of capacity as key to the successful management of their medications. Rather than concern for themselves at the present time they preferred to think of their involvement in the study as one of advocating for others in later life – some of whom they considered to be ‘old’. A number of approaches had been developed by individuals with a large degree of success being balanced with clear room for medication error. For almost all of the participants, their bespoke arrangements

worked well for them as far as could be discerned. Any changes in medication appearance presented a potential but manageable threat to their continued sense of control.

PART 5

Discussion

The findings suggest that although the participants generally felt that the changes in medication appearance were not a major *problem* for them, they were clearly expressing some *concerns* about the changes both for themselves and for others. The research team believes that the self-selecting sample of participants within this study reflect a section of the older adult population who are generally very competent at managing their medications so that a change in tablet appearance will likely not have too detrimental effect. The demands of partaking in a study involving interviews could be considered to lend themselves towards participants who are articulate, have sufficient experiences and issues to share and who are happy to discuss their successful medicines management practices. It may be that more vulnerable, less articulate participants, perhaps on the brink of difficulties with their medicines management or indeed having problems, may have been less likely to take part. Study Advisory Group members did feel that such a population is in existence and whom this particular study did not engage. If there is such a 'hidden' population then this needs considering for future enquiry aimed at understanding those at a higher risk from changed appearance of medications.

A significant theme that arose out of these interviews was the way in which 'being old' was interpreted and the impact this was seen to have on *control*. Whilst the study was focused with older adults, participants did not view themselves as old but did recognise that as a part of normal ageing, there may be a time when their ability to manage their medications and especially changed appearance of tablets may deteriorate. It was this potential shift towards having less capacity that concerned most participants rather than their current abilities to self-medicate. This finding supports our previously stated view that there is an untapped cohort of older adults in existence that have a reduced ability to take medications safely and who may be more vulnerable to being affected adversely by change in medication appearance. Several participants alluded to people they knew for whom this was the case and our own survey of older people indicated that there were

problems being experienced as a result of changes in tablet appearance (Williamson *et al* 2009).

The current regimens developed by the participants to manage their medication were varied, but reportedly led to good management and control of the medications for the vast majority of participants. Thus those in control of their tablets continued to maintain control despite any changes in medication appearance and if they had any concerns they were comfortable in gaining advice and knew where to get it. Whilst some did this, others relied on the patient instruction leaflets provided by manufacturers to check that the changed medications were correct and of the same content. These strategies led to a sense of confidence that supported participants in managing their medications.

The array of regimens followed by participants is in need of further investigation. Whilst there may be merit in the view 'if it works don't fix it', the regimens are challenged by changes in appearance of medications and sometimes significantly so. As a minimum, changes are concerning for all and in some cases disconcerting and anxiety provoking. Participants often recognised that whilst strategies worked for now, they may not do so as they become less able in later years. Future research could explore in detail why these regimens worked and how these people avoided the problems identified and experienced by others.

Some of the strategies employed to manage medicines could be considered to have a degree of risk attached to them by health care professionals especially. Participant's practice of removing medicines from their packaging on receipt for alternative means of storage is one example of a practice that pharmacists would not advocate but is not uncommon amongst those interviewed here. If as was found in this study, this is a common and long-established practice for some individuals, then one could reasonably expect it to continue into later life. This raises questions about whether there are better ways of identifying when somebody becomes at risk and whether better ways can be found to help people manage their medications other than home-grown ones. This is not suggested as a means of medicalising people's approaches, or replacing ones that genuinely work, merely one of wanting to explore whether there are some common measures that could be adopted that help certain groups. For example, the supplementary information sheet that accompanies Dosettes dispensed by some

pharmacists was found by some participants to be a very useful aid. Whether something along these lines could be used more widely is one possibility that could replace hand written lists of instructions produced by some participants and which could help support people through changes in medication appearance.

There was a clear demand for written information about medications that was fit for purpose. Prior notification about impending changes, simpler instruction leaflets inside packaging and Dosette information sheets are those most commonly highlighted by participants. Letters to communicate impending changes may be possible in some circumstances but for whom it would actually be cost effective in a risk *versus* benefit way, would need to be considered. The absence of instruction leaflets in some packaging and especially when medicines were received in a Dosette presented a missed opportunity for participants to keep informed. What was clear was that verbal information by pharmacists was very helpful as opposed to participants being handed a bag of medicines that were found to have changed on opening back at home. Helpful and consistent practice of this sort by pharmacists would clearly go a long way to alleviate concerns and anxiety. It is noted, however, that often pharmacists are themselves unaware of the changes, due to opaque, sealed or tamper-evident packaging preventing them from seeing the actual dosage form itself. Manufacturers should perhaps be required to notify pharmacists and explain changes, and to identify packages of products whose appearance has recently been altered. Pharmacy bodies have for many years called for manufacturers to standardise packaging in terms of quantity, be it a 28 day pack or 30 day. Addressing of this issue by manufacturers would also be helpful.

Whilst some participants avoided changes in medication appearance by sticking with the same pharmacy, this was not always possible. The inevitable occasional changes in medication appearance for reasons such as generic prescribing have clearly been found to cause widespread concern and at times anxiety. One interpretation of these findings is that there is a clear opportunity to identify who is at most risk from changed appearance of medications and to explore whether ways can be found to minimise the use of these practices with them.

Changes in medication appearance clearly affected participant's confidence in their own ability to self-manage medicines and it is believed that avoiding appearance changes with more at risk or anxious individuals and providing better information for them may be helpful in promoting greater confidence. Alongside this is a need to maintain independence wherever possible and to avoid the unintentional outcome of disempowering people who are managing to self-care successfully. How to identify those who would most benefit from this extra support needs exploring with health care professionals and others. As with Lowe's (2000) study involving medicines review and education interventions, participants in this study were not a homogenous group and the need to consider people's individual needs was very apparent.

Whilst effects on the person identified by this study are focused on anxiety, concern and confidence, these should not be dismissed as trivial. Indeed it is this same anxiety and concern that led Rochdale User Carer Action Forum members who themselves had experience of changed appearance of medications to go to great lengths to get this topic area looked at initially through local primary care governance processes in Rochdale and latterly through research.

Concerns about the sizes, packaging, access and quality of the tablets were highlighted during this study, but these were secondary compared with colour and shape issues and participant's need to demonstrate their control and awareness of their actual tablets. Whilst focusing primarily on appearance issues, the study did uncover insights that reinforce other's research as to the importance of medicines in the lives of older people. Fortunately much investment has already been made in exploring and improving medicines packaging and labelling, compliance and concordance and medication errors (Thompson *et al* 2006; Steinmetz *et al* 2005; Winfield & Bond 2004). What this study has added is a much needed insight into the little explored area of medication appearance and its effect on the lives of older people. The study findings affirm that medication appearance change is a particular concern of older people and is anxiety-provoking yet steps can be taken to help alleviate these effects.

PART 6

Conclusions & Recommendations

"You wouldn't buy an orange cabbage." (Trevor & Sarah)

Conclusions:

Three categories and an overarching core category emerged from the data. Those interviewed generally did not find that medication appearance change caused them major difficulty because they were able to manage the changes competently. Participants were very clear that changes in appearance did cause them significant concern and in some cases anxiety for a number of reasons. More importantly, those interviewed considered themselves not to be those most at risk from the changes as they had established their own informal medicines management approaches which generally worked for them. Participants were concerned for others who may be less competent and able than them. It is important to respect that these participants did experience negative effects from changed appearance of medications, although it is acknowledged that these were not presenting serious problems for most of this group. Participants did feel a number of their peers were at significantly more risk than them and that the experiences of these other older people require further investigation.

Participant's main concern was about the potential for them to lose capacity to manage their medicines in later life and how this would be identified as well as concern for those already with reduced capacity who may be being overlooked by health professionals who could address any risk.

Medication appearance changes compromised participant confidence at a personal level, with health professionals and in the medications themselves. Most felt they could overcome this reduced confidence by having routines that kept them in control of their regimes, by seeking advice and by reading routine or bespoke information about their medications. Participants agreed that high standards of practice by pharmacists should be encouraged to: avoid changes in appearance where possible; to notify people of changes where reasonable; and to avoid changes with those most at risk of being mal-affected by any changes. Further and better quality written information is also indicated as

these participants found instruction leaflets to be unhelpful whilst information sheets that accompany Dosettes issued by a pharmacist were considered to be very useful. Some would have preferred both kinds of information. Further work to engage with older people and perhaps develop information materials that meet their needs is indicated.

The widespread use of Dosette boxes purchased by participants without prompt from a health professional is suggestive that older people are feeling in need of support with their medication taking and is perhaps an early indicator of them having such a need. Whilst Dosettes issued by a pharmacist follow an assessment of need, those bought by individuals from high street shops do not and a Dosette box may not be the best solution for that individual's needs. This and other strategies to self-manage medications at home need further exploration especially as some approaches present more potential risk than others e.g. decanting medicines out of packaging into cups.

Colour changes were the most challenging changes in medication appearance for participants to manage as colour was often a key element to their informal medicines management routines. Shape was also an important factor which similarly helped participants identify medications especially when some were similarly coloured or there were many of them to take in a day. It may be helpful for pharmacists and other health professionals to be aware of *how* people specifically manage their medicines at home. Such knowledge would of course help identify those most at risk of errors from poor regimes but also help those who would benefit from consistency in medication appearance so that their existing regimes continue to work for them. Emphasis would be on maintaining those capable of self-care to do so for as long as possible.

This study has been valuable in that it complements our previous pan-Manchester survey of the same topic (Williamson *et al* 2009) which established evidence that many older people were experiencing anxiety, poor medicines management, upset, confusion, thus adding further to a very limited evidence base. Collectively we hope all these findings will prompt substantive further research into what we now believe is a widespread concern and problem of varying degrees amongst older people.

Of immediate concern to those who develop policy or provide healthcare services should be that these findings clearly show that some older people are being put at risk due to changed medication appearance. Whilst medicines management has especially been invested in during recent years by organisations such as Primary Care Trusts, we suggest a closer look is taken at the extent and nature of the key aspect of medicines management that these findings highlight, namely managing changes in appearance. Perhaps initiatives are needed that would accurately establish the number and nature of changes to individual's medication appearance (e.g. using pharmacy computer systems as opposed to patient recollection as with this study). This information could then be used towards identifying those patients who may be most vulnerable to medicines of altered appearance e.g. those experiencing frequent and / or multiple changes. This would be complemented by having a greater appreciation of informal medicines management strategies used by older people at home.

Particularly concerning is that at the time of finalising this report a Department of Health consultation is underway on Automated Generic Substitution (DH 2010). Proposals suggest options around the substitution of prescribed branded medicines with generic ones. Risks to certain groups such as older adults have been highlighted in a report (Baker *et al* 2009) where it is suggested that frequent and multiple changes to medication appearance as a result of generic substitution may be confusing. We intend to use the findings within our report to inform this consultation which is extremely timely

The implications for the roles of those who prescribe or dispense medicines, or those who have caring responsibilities for older people such as district nurses and those from partner agencies such as Local Authorities need to be considered. For example, pharmacists could seek ways of flagging up more vulnerable adults to GPs or possibilities for expanding the role of pharmaceutical home-delivery drivers could be considered. The widely reported good practice of pharmacists who have helped many respondents by sticking to a certain medication brand if the patient requests it is to be praised and reinforced. This good practice may have cost implications for the pharmacist and perhaps ways should be found to reimburse them. Similarly the approachability and helpfulness of pharmacists and their good practice in allaying anxiety by providing support and advice

regarding appearance changes is worth particular mention. Awareness raising and education for health care professionals could help them to support and educate older people to manage medicines that change appearance more effectively. We suggest that multi-disciplinary work is undertaken to explore: how older people can be better supported to maintain their informal medicines management strategies; how those at risk can be better identified; how individual needs can be better catered for; and how improved information can be developed and better provided.

Others would need to establish the cost implications of adjusting the current approaches of generic prescribing to avoid their use with those patients at most risk of making mistakes. This study is clearly too small and of too limited a focus to recommend adjustments to these practices. What we have shown is that concerns and anxiety are being experienced by unacceptable numbers of older people and we suspect that there are others who experience far greater effects and whom need to be engaged with in future study so that we can better understand their situation as a means of better supporting them and minimising risk.

Recommendations:

There are a number of aspects of these findings that would benefit from further collaborative enquiry through multi-disciplinary project work and / or further research.

- Multi-stakeholder working to examine information processes and to develop written information where needed: notification of change letters, information sheets, Medication Administration Report sheets, diagrammatic information
- Multi-stakeholder working to consider use of pictures - perhaps on boxes of medications - to support their correct identification by patients
- Requirement for manufacturers to notify pharmacists and explain changes, and to identify packages of products whose appearance has recently been altered plus standardised packaging in terms of quantity (28 or 30 day packs)
- Scoping of the individual strategies - formal and informal - that people use to manage their medicines at home as a means of identifying risk but also to inform possibilities

- around more selective dispensing of medication with changed appearance to those that will least be affected by it
- Examination of the roles, training / education needs and opportunities amongst community workers e.g. district nurses, pharmacists and GPs and partners such as Local Authorities in supporting older people with their medicines and identifying those most at risk e.g. vulnerable adults
 - Multi-stakeholder working to explore initiatives to accurately establish the frequency and nature of changes to individual's medication appearance as an aid to identifying those patients who may be most vulnerable to medicines of altered appearance e.g. those experiencing frequent and / or multiple changes
 - Economic analyses of generic prescribing practices including cost and quality of life implications
 - Exploration of the impact of changed appearance of medication with the wider older population including those who are less able to participate e.g. seldom heard or marginalised groups, those who are socially isolated and especially those at higher risk of negative effects such as those with reduced capacity to self manage medications
 - To allay anxiety, and encourage patients to communicate with their pharmacist, consider devising a poster that explains to patients 1) how large savings from generic prescribing are reinvested into patient services and 2) how when drugs come off patent, other manufacturers are free to produce them at lower cost, as long as they maintain efficacy 3) how pharmacists cannot order medicines from a specific manufacturer as it depends what wholesaler has in stock 4) the requirement to bulk some tablets up with excipients 5) the need for patients to talk to their pharmacist

APPENDIX



University of Salford
A Greater Manchester University

Study Number: 06/Q1410/142 Version 1 21/11/2006

Title of Project: **Older peoples' experiences of changed appearance of medications**

INTERVIEW GUIDE

1. Can you tell me about the prescribed tablet or capsule medicines you are currently taking?
2. Have you experienced any changes in your tablet or capsule medicines in recent months?
 - a. Can you tell me about those changes - probe nature, colour, size, shape, how much of a change from previous appearance
3. Do you have any of these tablets or capsules to show me?
4. Have the changes affected you in any way? - probe how - personally, ways medicines are stored, managed or taken etc
5. Have the changes presented you with any problems or challenges?
6. Have the changes been beneficial in any way?
7. Has the packaging of your tablets or capsules changed appearance in recent months?
 - a. Can you tell me about those changes - probe how - personally, how stored, managed or taken etc
8. Have you sought advice about any of these changes?
9. Have you taken tablets or capsules from any other source?
E.g. a neighbour in recent months - probe what and why

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